IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

UNITED STATES OF AMERICA,	No. <u>05</u> -
Plaintiff,)	COUNT ONE
v.)	Conspiracy to Sell Counterfeit,
(1) DOUGLAS C. ALBERS,	Illegally Imported, and Misbranded Drugs 18 U.S.C. § 371
[DOB XXXX/1951])	, and the second
All Counts)	NMT 5 Years Imprisonment
)	NMT \$250,000 Fine
(2) ALBERS MEDICAL)	NMT 3 Years Supervised Release
DISTRIBUTORS, INC.,	\$100 Special Assessment
All Counts)	Order of Restitution
)	Class D felony
(3) PAUL LOUIS KRIGER,)	COLINITATIVO
[DOB XXXX/1957], All Counts)	COUNT TWO
All Counts)	Congninger to Sall Stolen Drugg
(4) MICHAEL ALLYN CARLOW,)	Conspiracy to Sell Stolen Drugs 18 U.S.C. § 371
[DOB XXXX/1952],	16 U.S.C. § 371
Counts One, Two, Seven thru Nine,	NMT 5 Years Imprisonment
and Thirty-Six thru Fifty-three	NMT \$250,000 Fine
)	NMT 3 Years Supervised Release
(5) RICHARD K. ROUNSBORG,	\$100 Special Assessment
[DOB XXXX/1958],)	Order of Restitution
Counts One, Thirty-six thru Fifty-three)	Class D felony
)	
(6) MED-PRO, INC.,	COUNTS THREE through NINE
Counts One, Thirty-six thru Fifty-three	I
(7) CHRISTOPHER W. LAMOREALIN (Interstate Sale of Stolen Drugs
(7) CHRISTOPHER W. LAMOREAUX,)	18 U.S.C. §§ 2315 and 2
[DOB XXXX/1969], Counts One, Forty thru Forty-four,	As to each count:
Forty-nine thru Fifty-three	NMT 10 years imprisonment
)	\$250,000 fine
(8) NOAH SALCEDO-SMITH,	NMT 3 years supervised release
[DOB XXXX/1971],)	\$100 Special Assessment
Counts One thru Nine)	Order of Restitution
)	Class C felony
(9) H.D. SMITH WHOLESALE	
DRUG COMPANY,)	
Count One)	
(10) FRANK ANTHONY IANEILLO,)	COUNTS TEN thru FIFTEEN,

[DOB XXXX/1944], Counts Two thru Six)	TWENTY-TWO thru TWENTY-SEVEN, and THIRTY-FOUR thru FORTY-FOUR
Counts 1 wo thru 51x)	TIMET FOOK und FORTE FOOK
(11) GARY WAYNE SMITH,)	Sale of Counterfeit Drugs
[DOB XXXX/1968],)	21 U.S.C. § 331(i)(3) and 21 U.S.C. § 333(a)(2)
Counts Two thru Six)	21 0.6.0. 3 001(1)(0) and 21 0.6.0. 3 000(a)(2)
)	As to each count:
(12) ALBERT DAVID NASSAR,)	NMT 3 years imprisonment
[DOB XXXX/1955],)	\$250,000 fine
Counts Two thru Six)	NMT 3 years supervised release
)	\$100 Special Assessment
(13) SALVATORE A. ESPOSITO,)	Order of Restitution
[DOB XXXX/1958],)	Class E felony
Counts Two thru Six)	
)	COUNTS SIXTEEN thru TWENTY-ONE,
(14) ALEXANDER A. NASSAR,)	TWENTY-EIGHT thru THIRTY-THREE
[DOB XXXX/1963],)	
Counts One thru Six)	Sale of Misbranded Drugs
)	21 U.S.C. § 331(a) and 21 U.S.C. § 333(a)(2)
Defendants.)	
)	As to each count:
)	NMT 3 years imprisonment
)	\$250,000 fine
)	NMT 3 years supervised release
)	\$100 Special Assessment Order of Restitution
)	
)	Class E felony
)	COUNTS FORTY-FIVE thru FIFTY-THREE
)	COONTSTORTT-TIVE unuTHTT-TIMEE
)	Sale of an Unapproved New Drug
)	21 U.S.C. § 331(d) and 21 U.S.C. § 333(a)(2)
)	21 0.2.0. 3 001(0) 0.0.0. 3 000(0)(2)
)	As to each count:
)	NMT 3 years imprisonment
)	\$250,000 fine
)	NMT 3 years supervised release
)	\$100 Special Assessment
)	Order of Restitution
)	Class E felony

INDICTMENT

THE GRAND JURY CHARGES THAT:

At all times material and relevant to this Indictment:

INTRODUCTION and BACKGROUND

The Drug Distribution System in the United States

- 1. Drug manufacturers use a multi-tier system of wholesalers to distribute prescription drugs and pharmaceutical products ("drugs") in the United States. A few large companies with publicly traded stock occupy the top tier of the distribution system. These top-tier companies purchase drugs in huge volumes directly from a drug manufacturer. In turn, these top-tier companies sell to several large regional wholesalers. Below the regional wholesalers are a group known as secondary wholesalers who buy and sell drugs to and from each other and also sell drugs to hospitals, clinics, doctors, and pharmacies.
- 2. Drug manufacturers and pharmacy chains benefit from this multiple-tier distribution system because they centralize their sales and purchases and keep the cost of distributing drugs to a minimum. The volume purchases made by the top-tier wholesalers also create enormous sales numbers for the drug manufacturers which, in turn, help maintain or increase the value of the publicly-traded stock of the drug manufacturers.
- 3. A drug manufacturer will discount the price of a particular drug as a way to increase a drug's market share and provide the drug to additional patients. For example, drug manufacturers offer price discounts to buyers who agree not to resell a drug and to buyers who agree to sell a drug in a foreign country. Because of the ability to offer price discounts, a particular drug can frequently be purchased at different prices in the secondary wholesale market.
- 4. The secondary wholesale market is characterized by aggressive trading in which the wholesalers look to buy low and sell high. Many persons monitor the secondary wholesale market

looking for opportunities to make money by purchasing discounted drugs. The large regional wholesalers buy from secondary wholesalers when there is a shortage of a particular drug and sell to secondary wholesalers when there is an oversupply of a particular drug. It is not uncommon for a drug to pass through multiple secondary wholesalers prior to it being purchased by a consumer.

5. Buying and selling drugs in the secondary wholesale market is not *per se* illegal. However, the fact that a particular type of drug can be bought or sold for multiple prices creates an opportunity for unscrupulous wholesalers to exploit the secondary wholesale market by resorting to fraud and misrepresentation when buying or selling a drug. For example, drugs purchased at a discount based on the promise not to resell them are, in fact, resold on the secondary wholesale market. Drugs obtained at a discount price based on the promise that they will be sold in a foreign country are, instead, sold in the United States. These practices are referred to as "diversion." In other instances, a secondary wholesaler will turn a blind eye to the corrupt or illegal practices of another secondary wholesaler that is offering drugs for sale in the secondary wholesale market. The secondary wholesale market also provides unscrupulous wholesalers with a gateway to introduce counterfeit and stolen drugs into the drug distribution system.

Laws and Regulations

- 6. One of the ways Congress sought to prevent this potential fraud was to require that wholesalers furnish their buyers with a written statement identifying the persons and entities from whom the drug was purchased. Within the wholesale drug industry, this written statement is referred to as a "pedigree." Unscrupulous wholesalers frequently circumvent the pedigree requirement by simply creating phony pedigrees that misrepresent the origin and history of the drug being sold.
- 7. Another way Congress sought to prevent America's drug supply from being compromised was by enacting legislation, such as the Federal Food, Drug, and Cosmetic Act

(FDCA), Title 21, United States Code, Section 301, et seq. In enacting the FDCA, Congress determined that the public interest in the purity of prescription drugs and pharmaceutical products distributed to American consumers is so great as to warrant imposition of the highest standard of care on those who distribute those products to the public. Under the FDCA, the responsibility for maintaining the quality and safety of drugs is not placed on the innocent public that purchases drugs but rather, that responsibility is placed on those who sell and distribute drugs. Under the FDCA, consumers have a right to expect that drug distributors will be vigilant and responsible in matters that affect the public health and well-being, and that drug distributors will, among other things, verify the source and origin of the drugs they buy and sell to the public, and truthfully disclose the source and origin of the drugs they sell to the public.

The Defendants

- 8. Defendant Douglas C. Albers (Albers) was a trained pharmacist, licensed as such by the State of Missouri, who owned and operated defendant Albers Medical Distributors, Inc. (Albers Medical), a wholesale pharmacy licensed as such by the State of Missouri that was located at 4400 Broadway, Kansas City, Missouri. Defendant Albers used Defendant Albers Medical to buy and sell drugs in the secondary wholesale drug market. Defendant Albers controlled the operation of Albers Medical and was in charge of Albers Medical on a daily basis. By reason of his position as the owner and operating pharmacist of Albers Medical, defendant Douglas C. Albers had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 9. Defendant Paul Louis Kriger owned and operated OTS Sales, Inc. Defendant Kriger used OTS Sales, Inc., to buy and sell drugs in the secondary wholesale drug market on behalf of

defendants Douglas C. Albers and Albers Medical Distributors, Inc. Defendant Kriger controlled the operation of OTS Sales, Inc., and was in charge of OTS Sales, Inc., on a daily basis. By reason of his position as the owner and operator of OTS Sales, Inc., defendant Kriger had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.

- 10. Defendant Noah Salcedo-Smith worked for defendant Paul Kriger and was involved in the day-to-day operation of OTS Sales, Inc. By reason of his involvement in the operation of OTS Sales, Inc., defendant Noah Salcedo-Smith had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 11. Defendant Michael Allyn Carlow operated and controlled a company known as G&K Pharma that was used to buy and sell drugs in the secondary wholesale drug market. By reason of his control over G&K Pharma, defendant Carlow had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 12. Defendant Richard K. Rounsborg was the owner and corporate president of defendant Med-Pro, Inc., a privately-held corporation organized under the laws of the State of Nebraska, doing business from premises located at 210 East Fourth, Lexington, Nebraska 68850. Med-Pro, Inc., was engaged in the business of repackaging, distributing, and selling pharmaceutical products and drugs. According to Med-Pro's website (www.med-pro-inc.com), it was the "premier privately-held pharmaceutical repackaging company" in the United States and does business nationwide. By reason of his control over Med-Pro, Inc., defendant Rounsborg had the responsibility and authority

- to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 13. Defendant Christopher W. Lamoreaux was the President and CEO of NuCare Pharmaceuticals, Inc., a California-based company engaged in the business of repackaging pharmaceutical drugs and products. By reason of his position at NuCare Pharmaceuticals, defendant Lamoreaux had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 14. Defendant H.D. Smith Wholesale Drug Company was a corporate entity based in the State of Illinois that was engaged in the business of buying and selling drugs in the secondary wholesale drug market. Defendant H.D. Smith Wholesale Drug Company authorized various employees and agents to act on its behalf in the secondary wholesale drug market to include Diana S. Coelyn. Defendant H.D. Smith was legally responsible for the actions taken by the agents and employees authorized to act on its behalf in the secondary wholesale drug market.
- 15. Defendant Frank Anthony Ianeillo operated and controlled a company known as Welcome Rx that was used to buy and sell drugs in the secondary wholesale drug market. Defendant Ianeillo was in charge of Welcome Rx on a daily basis. By reason of his control over Welcome Rx, defendant Ianeillo had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 16. Defendant Gary Wayne Smith operated and controlled a company known as Omega Pharmaceuticals that was used to buy and sell drugs in the secondary wholesale drug market. Defendant Smith was in charge of Omega Pharmaceuticals on a daily basis. By reason of his control

over Omega Pharmaceuticals, defendant Smith had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.

- 17. Defendants Albert David Nassar and Salvatore A. Esposito controlled, operated, and were involved in the operation of a company known as Worldwide Pharmaceuticals that was used to buy and sell drugs in the secondary wholesale drug market. By reason of their involvement in the operation of Worldwide Pharmaceuticals, defendants Albert David Nassar and Salvatore A. Esposito had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.
- 18. Defendant Alexander Anthony Nassar controlled, operated, and was involved in the operation of a company known as New Horizons LLC that was used to buy and sell drugs in the secondary wholesale drug market. By reason of his involvement in the operation of New Horizons LLC, defendant Alexander Anthony Nassar had the responsibility and authority to: (1) prevent violations of the FDCA in the first instance; (2) promptly correct any violations of the FDCA; and (3) insure that violations of the FDCA did not occur in the future.

Albers Medical Distributors, Inc., Repeatedly Sold Drugs in Violation of Law

19. On or about May 8, 2000, and again on May 15, 2000, an inspector from the Missouri State Board of Pharmacy conducted an inspection at the business premises of defendant Albers Medical Distributors, Inc., in Kansas City, Missouri. Said inspections documented that defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., had purchased drugs from forty-four (44) out-of-state distributors who were not licensed to ship drugs into the state of Missouri, thereby

violating Missouri State law requiring that those who ship drugs into the state of Missouri be licensed to do so by the State of Missouri.

- 20. On or about November 16, 2000, an inspector from the Missouri State Board of Pharmacy conducted an inspection at the business premises of defendant Albers Medical Distributors, Inc., in Kansas City, Missouri. Said inspection documented that since the previous inspection on May 15, 2000, defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., had continued to violate Missouri State law by purchasing drugs from seventeen (17) of the forty-four (44) out-of-state distributors identified in the May 2000 inspections. These seventeen (17) unlicensed distributors were represented on ninety-eight (98) invoices involving sales of more than \$3,000,000.00 (three million dollars) worth of drugs.
- 21. On or about December 5, 2000, the Missouri State Board of Pharmacy sent defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., a written notice warning him that continued purchases from distributors who were not licensed by the State of Missouri was a serious violation of Missouri state law. Defendant Douglas C. Albers was admonished to immediately cease doing business with unlicensed distributors.
- 22. Despite this clear and unequivocal written warning and admonishment, during an inspection on or about September 19, 2001, an inspector from the Missouri State Board of Pharmacy documented that since December 5, 2000, defendant Douglas C. Albers, d/b/a/ Albers Medical Distributors, Inc., had purchased drugs from four (4) out-of-state distributors who were not licensed by the State of Missouri, thereby violating Missouri State law requiring that those who ship drugs into the state of Missouri be licensed to do so by the State of Missouri.
- 23. On or about March 5, 2002, an inspector from the Missouri State Board of Pharmacy conducted an inspection at the business premises of defendant Albers Medical Distributors, Inc., in

Kansas City, Missouri. Said inspection documented that since September 19, 2001, defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., had purchased drugs from twelve (12) out-of-state distributors who were not licensed to ship drugs into the state of Missouri, thereby violating Missouri State law requiring that those who ship drugs into the state of Missouri be licensed to do so by the State of Missouri. Some of the twelve (12) unlicensed distributors identified during the March 5, 2002, inspection were distributors who had been identified in previous inspections as not being licensed by the State of Missouri.

- 24. On or about June 10, 2002, an inspector from the Missouri State Board of Pharmacy conducted an inspection at the business premises of defendant Albers Medical Distributors, Inc., in Kansas City, Missouri. Said inspection documented that since March 5, 2002, defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., had purchased drugs from five (5) out-of-state distributors who were not licensed to ship drugs into the state of Missouri, thereby violating Missouri State law requiring that those who ship drugs into the state of Missouri be licensed to do so by the State of Missouri.
- 25. On or about June 10, 2002, an inspector from the Missouri State Board of Pharmacy randomly selected seven pedigrees from the business records of defendant Albers Medical Distributors, Inc., for the purpose of verifying the authenticity of the pedigrees. The validity of six of the seven pedigrees could not be verified.
- 26. On or about December 16, 2002, defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., sold a quantity of the drug Zyprexa in interstate commerce, and furnished a pedigree that falsely stated the origin of the Zyprexa.

- 27. On or about February 12, 2003, defendant Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., sold a quantity of the drug Zyprexa in interstate commerce, and furnished a pedigree that falsely stated the origin of the Zyprexa.
- 28. On or about September 26, 2003, the Missouri State Board of Pharmacy suspended for thirty (30) days the license of defendant Albers Medical Distributors, Inc., to distribute drugs in the State of Missouri.

Michael Allyn Carlow Has a History of Distributing Drugs in Violation of Law

three years in prison. In 1998, defendant Carlow obtained a license from the State of Florida to engage in the wholesale drug distribution business. Following his arrest in June 2000 for buying \$90,000.00 worth of stolen drugs, defendant Carlow pled guilty, was sentenced to eighteen months probation, and surrendered his Florida state license to engage in the wholesale drug distribution business. Thereafter, defendant Carlow continued to engage in the wholesale drug distribution business by using friends, acquaintances, and family members as fronts to disguise his personal involvement in the operation and control of companies engaged in the wholesale drug distribution business. On or about July 21, 2003, defendant Carlow was arrested in the State of Florida and charged with multiple counts of racketeering and conspiracy to commit racketeering in violation of Florida state law. Said charges pertain to defendant Carlow's activities in the secondary wholesale drug market. Said charges are still pending and defendant Carlow remains in state custody in Florida pending trial.

Gary Wayne Smith's Company Distributed Drugs in Violation of the Law

30. In or about June 2004, in the United States District Court for the Southern District of Alabama, Omega Pharmaceuticals, the company operated and controlled by defendant

Gary Wayne Smith, pled guilty to and was convicted of the misdemeanor offense of selling and holding for sale counterfeit drugs. Defendant Gary Wayne Smith signed both a written plea agreement and a written factual basis submitted to the court on behalf of Omega Pharmaceuticals. In the written factual basis, defendant Gary Wayne Smith admitted that Omega Pharmaceuticals sold and held for sale eleven different counterfeit drugs.

Christopher Wayne Lamoreaux Took Illegal Kickbacks From Douglas C. Albers

31. In or about July 2004, in the United States District Court for the Western District of Missouri, defendant Christopher Wayne Lamoreaux was convicted by jury verdict of two counts of mail fraud, based on his receipt of illegal kickbacks from defendants Douglas C. Albers and Paul Louis Kriger. On or about November 2004, defendant Christopher Wayne Lamoreaux was sentenced to a 21-month prison term, which he is currently serving.

Diana S. Coelyn Took Illegal Kickbacks From Douglas C. Albers

32. In or about April 2004, in the United States District Court for the Western District of Missouri, Diana S. Coelyn pled guilty to three counts of mail fraud and six counts of wire fraud, all of which were based on her receipt of illegal kickbacks from defendants Douglas C. Albers and Paul Louis Kriger. Diana S. Coelyn is awaiting sentencing.

Co-Conspirators Who Have Admitted Participation in the Illegal Distribution of Drugs

- 33. Numerous persons, as identified in the following paragraphs, have been prosecuted for their roles in a conspiracy to distribute counterfeit and illegally imported Lipitor[®].
- 34. In or about January 2005, in the United States District Court for the Western District of Missouri, Julio Cesar Cruz waived indictment and pled guilty to a three-count Information charging him with conspiracy to sell counterfeit and illegally imported Lipitor® and two substantive

counts of the unlawful sale of counterfeit Lipitor® with the intent to defraud and mislead. Cruz is awaiting sentencing.

- 35. In or about February 2005, in the United States District Court for the Western District of Missouri, Domingo Gonzalez waived indictment and pled guilty to a three-count Information charging him with conspiracy to sell counterfeit and illegally imported Lipitor® and two substantive counts of the unlawful sale of counterfeit Lipitor® with the intent to defraud and mislead. Gonzalez is awaiting sentencing.
- 36. In or about March 2005, in the United States District Court for the Western District of Missouri, Richard Paul Goodman pled guilty to a single count Indictment charging him with conspiracy to sell counterfeit and illegally imported Lipitor®. Goodman is awaiting sentencing.
- 37. In or about February 2005, Gregory A. Broccoli was charged in a single count Indictment with conspiracy to sell counterfeit and illegally imported Lipitor[®]. According to the court file in the Western District of Missouri, Broccoli was arrested and had an initial appearance in the

District of New Jersey. He waived his right to a Rule 40 identity hearing and was released on bond. On April 25, 2005, Broccoli consented to transfer the Western District of Missouri case to the District of New Jersey for the purpose of entering a guilty plea. On April 26, 2005, the Western District of Missouri case was transferred to the District of New Jersey. Proceedings for entry of the guilty plea in the District of New Jersey are pending.

38. In or about August 2005, in the United States District Court for the Western District of Missouri, Maria Eugenia Medina Milgrom waived indictment and pled guilty to a single count Information charging her with conspiracy to sell counterfeit and illegally imported drugs. Milgrom is awaiting sentencing.

The United States Food and Drug Administration

39. The United States Food and Drug Administration (FDA) is an agency of the United States government responsible for, among other things: (a) ensuring that drugs intended for use by humans bear true and accurate information and are safe and effective for their intended uses; (b) preventing the sale and distribution of drugs not approved for sale and distribution in the United States; (c) regulating the interstate sale and distribution of drugs; and (d) generally protecting the health and safety of American consumers who purchase drugs.

COUNT ONE

(Conspiracy to Sell Counterfeit, Illegally Imported, and Misbranded Drugs)

The factual allegations in Paragraphs One through Thirty-Nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.

The Conspiracy and Its Objects

Beginning at a time unknown, but by no later than in or about February 2002, and continuing until at least in or about April 2003, in Kansas City, Jackson County, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Michael Allyn Carlow, Noah Salcedo-Smith, Christopher W. Lamoreaux, Richard K. Rounsborg, Med-Pro, Inc., H.D. Smith Wholesale Drug Company, and Alexander A. Nassar did unlawfully, willfully and knowingly combine, conspire and agree with each other and with others known and unknown to the grand jury to: (a) commit offenses against the United States, that is, purchase and sell counterfeit, misbranded, and illegally imported drugs, in violation of the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301 et seq., and (b) defraud the United States by impeding, obstructing, and defeating the lawful functions of the FDA to: (i) prevent the sale and distribution of drugs not approved for sale and distribution in the United States; (ii) regulate the interstate sale and distribution of drugs in the United States; and, (iii) safeguard the health and safety of consumers who purchase drugs in the United States, in that the members of the conspiracy, by mutual agreement and with the intent to defraud and mislead, would and did cause the manufacture, importation, labeling, and repackaging of certain drugs; cause the misbranding and counterfeiting of certain drugs; and sell certain misbranded and counterfeited drugs, all in violation of Title 18, United States Code, Section 371.

Manner and Means By Which The Conspiracy Was Carried Out

The members of the conspiracy used various manners and means to effect the object and purpose of the conspiracy, including but not limited to the following:

- 1. It was a part of the conspiracy that Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States were illegally imported into the United States ("illegally imported tablets" or "diverted tablets") by, among other things, making false and fraudulent representations to the United States Customs Service.
- 2. It was further a part of the conspiracy that Pfizer-manufactured Celebrex® capsules not intended or approved for sale in the United States were illegally imported into the United States ("illegally imported tablets" or "diverted tablets") by, among other things, making false and fraudulent representations to the United States Customs Service.
- 3. It was further a part of the conspiracy that various chemicals were purchased for use in manufacturing counterfeit tablets intended to be similar to Pfizer-manufactured Lipitor® tablets.
- 4. It was further a part of the conspiracy that punches and dies were purchased for use in manufacturing counterfeit tablets intended to be similar to Pfizer-manufactured Lipitor® tablets.
- 5. It was further a part of the conspiracy that said punches, dies, and chemicals were shipped to locations outside the United States for the purpose of setting up a drug manufacturing facility in a foreign country.
- 6. It was further a part of the conspiracy that counterfeit tablets similar to Pfizer-manufactured Lipitor® tablets ("counterfeit tablets") were manufactured in a foreign country.
- 7. It was further a part of the conspiracy that said counterfeit tablets were illegally imported into the United States by, among other things, making false and fraudulent representations to the United States Customs Service.

- 8. It was further a part of the conspiracy that counterfeit labels intended to be similar to the labels on bottles containing Pfizer-manufactured Lipitor® were manufactured in the United States.
- 9. It was further a part of the conspiracy that its members would and did cause the counterfeit, illegally imported, and diverted tablets to be repackaged with the intent to misbrand them, conceal their true nature as counterfeit, illegally imported, and diverted tablets, and prevent their detection as counterfeit, misbranded, illegally imported, and diverted tablets.
- 10. It was further a part of the conspiracy that its members would and did create false pedigrees in an effort to conceal the nature of the counterfeit, illegally imported, and diverted tablets, and prevent their detection as counterfeit, misbranded, illegally imported, and diverted tablets.
- 11. It was further a part of the conspiracy that its members intended to impede, obstruct, and defeat the lawful functions of the FDA to prevent the sale and distribution of drugs not approved for sale and distribution in the United States, regulate the interstate sale and distribution of drugs, and safeguard the health and safety of consumers who purchase drugs, by selling the counterfeit, misbranded, illegally imported, and diverted tablets in the United States as Pfizer-manufactured Lipitor® tablets intended and approved for sale in the United States.

Overt Acts

In furtherance of the conspiracy to traffic in counterfeit, misbranded, and illegally imported drugs and to accomplish the objects of the conspiracy, one or more members of the conspiracy committed and caused to be committed various overt acts within the Western District of Missouri and elsewhere including, but not limited to, the following:

- 1. In or about June 2002, various members of the conspiracy purchased excipients to be used in the manufacture of counterfeit Lipitor® and caused the excipients to be shipped to a location in Costa Rica.
- 2. In or about August 2002, various members of the conspiracy ordered punches and dies from a company in the St. Louis, Missouri area, to be used for the manufacture of 10 mg. and 20 mg. counterfeit Lipitor® tablets.
- 3. In or about September 2002, various members of the conspiracy caused the punches and dies purchased from the St. Louis, Missouri area company to be shipped to Costa Rica via Miami, Florida.
- 4. In or about October 2002, various members of the conspiracy purchased excipients to be used in the manufacture of counterfeit Lipitor® and caused the excipients to be shipped to a location in Costa Rica.
- 5. On three separate occasions in November 2002, various members of the conspiracy purchased excipients to be used in the manufacture of counterfeit Lipitor® and caused the excipients to be shipped to a location in Costa Rica.
- 6. In or about January 2003, various members of the conspiracy purchased excipients to be used in the manufacture of counterfeit Lipitor® and caused the excipients to be shipped to a location in Costa Rica.
- 7. Between in or about October 2002 and November 2002, various members of the conspiracy ordered and purchased counterfeit drug labels from a company in the greater Miami, Florida area, with the intent to misbrand the counterfeit, illegally imported, and diverted tablets by placing the counterfeit labels on bottles containing said tablets.

- 8. On or about March 4, 2003, Julio Cesar Cruz, acting at the direction of defendant Paul Louis Kriger, directed Iggy Santisteban to create a black and white label to be placed on bottles containing purported Lipitor® and Bextra® tablets.
- 9. On or about March 13, 2003, Julio Cesar Cruz, acting at the direction of defendant Paul Louis Kriger, directed Iggy Santisteban to create a black and white label to be placed on bottles containing purported Lipitor® and Bextra® tablets.
- 10. On or about March 25, 2003, Julio Cesar Cruz, acting at the direction of defendant Paul Louis Kriger, directed Iggy Santisteban to create a black and white label to be placed on bottles containing purported Lipitor® tablets.

On or about the dates listed below, members of the conspiracy used the entity listed below to purchase, in the approximate amounts listed below, Pfizer-manufactured Lipitor® product, manufactured for distribution in a South American country and not approved for sale in the United States, with the intent to illegally import the South American Lipitor® into the United States:

Overt Act Number	Date	Entity	Amount
11	July 31, 2002	Pharma Medical	\$1,142,774.52
12	August 27, 2002	Pharma Medical	\$1,005,317.42
13	October 2, 2002	Lighthouse Investments	\$1,787,092.19
14	October 25, 2002	Import & Export Sulamericanas SA	\$3,297,916.25
15	December 5, 2002	Import & Export Sulamericanas SA	\$1,322,547.61

16. In the eleven month time period between May 8, 2002, and April 4, 2003, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger, paid G& K Pharma in excess of \$42 million to purchase drugs from defendant Michael Allyn Carlow.

On or about the dates listed below, defendant Albers Medical Distributors, Inc., using a bank account located within the Western District of Missouri, paid the approximate amounts listed below to defendant Michael Allyn Carlow, by causing said sums to be deposited into a bank account controlled by defendant Michael Allyn Carlow and held in the name of G&K Pharma at banks in Maryland and Florida, which money was used to purchase counterfeit, misbranded, illegally imported, and diverted tablets from other members of the conspiracy:

Overt Act Number	Date	Amount
17	November 15, 2002	\$1,446,304.65
18	November 26, 2002	\$1,439,227.93
19	December 3, 2002	\$1,404,000.00
20	December 10, 2002	\$1,425,060.00
21	December 20, 2002	\$2,200,553.00
22	January 9, 2003	\$2,118,186.00
23	January 30, 2003	\$1,347,230.57
24	February 24, 2003	\$1,684,259.36
25	March 19, 2003	\$1,031,846.05
26	April 4, 2003	\$2,586,183.20

On or about the dates listed below, monies from bank accounts controlled by defendant Michael Allyn Carlow and held in the name of G&K Pharma, were deposited in the approximate amounts listed below into a bank account controlled by Julio Cesar Cruz and held in

the name of Pharma Medical at a bank in Tennessee, which money represented proceeds from the sale of the counterfeit, misbranded, illegally imported, and diverted tablets by members of the conspiracy:

Overt Act Number	Date	Amount
27	November 18, 2002	\$1,398,079.65
28	November 27, 2002	\$1,382,321.15
29	December 9, 2002	\$1,248,606.00
30	December 11, 2002	\$1,368,835.00
31	December 23, 2002	\$2,117,757.00
32	January 9, 2002	\$2,038,452.00
33	February 4, 2003	\$1,293,542.00

On or about the dates listed below, monies from bank accounts controlled by defendant Michael Allyn Carlow were deposited in the approximate amounts listed below into a bank account in the name of New Horizons controlled by defendant Alexander A. Nassar, which money represented proceeds from the sale of the counterfeit, misbranded, illegally imported, and diverted tablets by members of the conspiracy:

Overt Act Number	Date	Amount
34	February 27, 2003	\$900,000.00
35	February 28, 2003	\$276,619.00
36	March 24, 2003	\$792,000.00
37	March 25, 2003	\$200,161.00
38	April 8, 2003	\$1,150,000.00

Overt Act Number	Date	Amount
39	April 15, 2003	\$800,000.00

- 40. Between in or about June and July 2002, defendants Richard K. Rounsborg and Med-Pro, Inc., received a shipment containing 200 mg. Celebrex® capsules that were not approved for sale or distribution in the United States and that had been illegally imported into the United States by other members of the conspiracy. The inserts accompanying said Celebrex® capsules were written in Portuguese.
- 41. In or about June 2002, defendants Richard K. Rounsborg and Med-Pro, Inc., submitted a sample of the illegally imported Celebrex® capsules to a company in Maryland Heights, Missouri, and requested that the product be tested to determine if it contained the active ingredient in Celebrex® capsules that were approved for sale and distribution in the United States.
- 42. Between in or about June and July 2002, defendants Richard K. Rounsborg and Med-Pro, Inc., repackaged the illegally imported 200 mg. Celebrex® capsules with the intent to misbrand said capsules by removing the Portuguese inserts and thereby conceal the true origin of the illegally imported capsules and prevent their detection as illegally imported and diverted capsules that were not approved for sale and distribution in the United States.
- 43. On three separate dates in July 2002, defendants Richard K. Rounsborg and Med-Pro, Inc., submitted invoices to defendant Albers Medical Distributors, Inc., requesting payment for repackaging the illegally imported Celebrex[®].
- 44. On or about June 25, 2002, defendant Albers Medical Distributors, Inc., using a bank account located within the Western District of Missouri, paid defendants Richard K. Rounsborg and Med-Pro, Inc., the sum of \$4,000.00 in payment for repackaging the illegally imported Celebrex[®].

- 45. On or about July 10, 2002, defendant Albers Medical Distributors, Inc., using a bank account located within the Western District of Missouri, paid defendants Richard K. Rounsborg and Med-Pro, Inc., the sum of \$3,049.00 in payment for repackaging the illegally imported Celebrex[®].
- 46. On or about August 14, 2002, defendant Albers Medical Distributors, Inc., using a bank account located within the Western District of Missouri, paid defendants Richard K. Rounsborg and Med-Pro, Inc., the sum of \$5,466.23 in payment for repackaging the illegally imported Celebrex[®].
- 47. Between in or about June and July 2002, defendants Richard K. Rounsborg and Med-Pro, Inc., introduced and delivered for introduction into interstate commerce the repackaged and misbranded 200 mg. Celebrex® capsules by causing them to be shipped to locations outside the State of Nebraska including, by way of illustration and not by way of limitation, the State of Illinois.

On or about the dates listed below, defendants Richard K. Rounsborg and Med-Pro, Inc., received a shipment of counterfeit, misbranded, and illegally imported drugs that had been sent and delivered in interstate commerce by a private, commercial interstate carrier, namely, United Parcel Service, with the shipment being sent from a location in the State of Florida to Med-Pro, Inc., in the State of Nebraska, using the United Parcel Service account number assigned to the entity indicated below:

Overt Act Number	Date	Account Holder
48	November 14, 2002	Albers Medical Distributors, Inc. and Albers Medical, Inc.
49	November 22, 2002	Albers Medical Distributors, Inc. and Albers Medical, Inc.

Overt Act Number	Date	Account Holder
50	December 2, 2002	Albers Medical Distributors, Inc. and Albers Medical, Inc.
51	December 12, 2002	Albers Medical Distributors, Inc. and Albers Medical, Inc.
52	January 15, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
53	January 23, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
54	February 5, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
55	February 14, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
56	March 14, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
57	March 17, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
58	March 18, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.
59	March 20, 2003	Albers Medical Distributors, Inc. and Albers Medical, Inc.

- 60. In or about January 2003, defendants Richard K. Rounsborg and Med-Pro, Inc., submitted a sample of the counterfeit and illegally imported Lipitor® tablets to a company in Maryland Heights, Missouri, and requested that the product be tested to determine if it contained the active ingredient in Lipitor® tablets that were approved for sale and distribution in the United States.
- 61. Between in or about November 2002 and April 2003, defendants Richard K. Rounsborg and Med-Pro, Inc., repackaged the counterfeit and illegally imported Lipitor® tablets

with the intent to misbrand said tablets by concealing the true origin of the illegally imported tablets and preventing their detection as counterfeit, illegally imported, and diverted tablets that were not approved for sale or distribution in the United States.

On or about the dates listed below, defendant Albers Medical Distributors, Inc., using a bank account located within the Western District of Missouri, paid defendants Richard K. Rounsborg and Med-Pro, Inc., the approximate amounts listed below as payment for repackaging illegally imported, counterfeit, and misbranded drugs.

Overt Act Number	Date	Amount
62	November 26, 2002	\$11,435.56
63	December 18, 2002	\$29,374.78
64	January 23, 2003	\$23,856.01
65	February 10, 2003	\$18,470.75
66	March 3, 2003	\$11,188.00
67	March 7, 2003	\$17,509.81
68	March 17, 2003	\$15,588.25
69	March 31, 2003	\$27,835.20
70	April 7, 2003	\$18,141.33

- 71. Between in or about November 2002 and April 2003, defendants Richard K. Rounsborg and Med-Pro, Inc., introduced and delivered for introduction into interstate commerce the repackaged, illegally imported, counterfeit, and misbranded Lipitor® tablets by causing them to be shipped to locations outside the State of Nebraska including, by way of illustration and not by way of limitation, the State of Illinois.
- 72. In or about April 2003, defendant Richard K. Rounsborg, acting both in his individual capacity and in his capacity as an agent of defendant Med-Pro, Inc., attempted to prevent and

obstruct federal law enforcement agents from learning about the conspiracy when he falsely stated to said federal law enforcement agents that all the purported Lipitor® received by Med-Pro, Inc., had arrived in bottles with labeling prepared by the lawful manufacturer of Lipitor® whereas, in truth and in fact as defendant Richard K. Rounsborg then and there well knew, much of the purported Lipitor® received by Med-Pro, Inc., had arrived in containers with a generic black and white label which defendant Richard K. Rounsborg knew had not been prepared by the lawful manufacturer of Lipitor®, and which defendant Richard K. Rounsborg further knew was an indication that the purported Lipitor® was not approved for sale or distribution in the United States.

- 73. In or about June 2002, acting in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Paul Louis Kriger to discuss the repackaging by defendants Richard K. Rounsborg and Med-Pro, Inc., of illegally imported Celebrex® that had inserts written in Portuguese.
- 74. In or about December 2002, acting in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Richard K. Rounsborg to discuss his receipt of bulk Lipitor® in bottles with black and white printed labels that were dirty and smeared. Thereafter, and again in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Paul Louis Kriger during which the decision was made to continue repackaging the purported Lipitor® despite their concerns that the product had been illegally diverted.
- 75. In or about January 2003, acting in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Richard K. Rounsborg to discuss his receipt of bulk Lipitor® in which some of the bottles contained pieces of tin foil. During this telephone conversation, Rounsborg told Coelyn that the tin foil was thin and

appeared to have come from blister-packs. Thereafter, and again in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Douglas C. Albers during which Coelyn told Albers that Rounsborg had received bulk Lipitor® that contained tin foil from blister-packs. Despite the fact that it was obvious to both Coelyn and defendant Albers that this product had been illegally diverted, defendant Albers instructed Coelyn to have Rounsborg repackage the suspect Lipitor®. Thereafter, and again in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Coelyn had a telephone conversation with defendant Paul Louis Kriger regarding defendant Rounsborg's receipt of bulk Lipitor® that contained tin foil from blister-packs.

- 76. Sometime during the first few months of 2003, acting in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Paul Louis Kriger, in which Kriger stated that he had worked a deal with defendant Michael Allyn Carlow and Carlow's company, G&K Pharma, to "kosherize the paper trail" for the illegally imported, misbranded, and counterfeit Lipitor® Albers Medical Distributors, Inc., was selling to H.D. Smith Wholesale Drug Company. Within the secondary wholesale drug business, "kosherizing" is code for making a paper trail or pedigree appear to be legitimate when it is not.
- 77. Sometime in early 2003 and after the receipt of bulk Lipitor® containing tin foil, and again acting in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Richard K. Rounsborg to discuss his receipt of bulk Lipitor® in which some of the bottles contained 20 milligram tablets mixed with 40 milligram tablets. Thereafter, and again in her capacity as an agent of defendant H.D. Smith Wholesale Drug Company, Diana S. Coelyn had a telephone conversation with defendant Paul Louis Kriger during which Kriger stated "the feds will nail us" and "our tits are in a ringer."

- 78. In or about January 2003, defendants Paul Louis Kriger, Michael Allyn Carlow, and Noah Salcedo-Smith caused the issuance of pedigree papers that falsely stated the source and origin of the counterfeit, illegally imported, and misbranded Lipitor® being sold and distributed by the members of the conspiracy.
- 79. Between in or about February 2003 and June 2003, defendant Alexander Anthony Nassar caused the creation of pedigree papers that falsely stated the source and origin of the counterfeit, illegally imported, and misbranded Lipitor® being sold and distributed by the members of the conspiracy.
- 80. In or about November 2002, defendant Christopher Wayne Lamoreaux agreed with defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger to remove the drug Coumadin from blister packages marked "for hospital use only" and repackage the drugs in bulk plastic bottles that would disguise and conceal the fact that the Coumadin was "for hospital use only."
- 81. Between in or about November 2002 and March 2003, defendant Christopher Wayne Lamoreaux agreed with defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger to repackage purported Bextra® and Lipitor®.

On or about the dates listed below, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger paid secret commissions and kickbacks to defendant Christopher Wayne Lamoreaux and his designee in the approximate amounts listed below:

Overt Act Number	Date	Amount of Kickback
82	February 7, 2003	\$6,815.22
83	March 26, 2003	\$108,463.32

Between in or about July 2002 and March 2003, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger paid more than \$400,000.00 in secret commissions and kickbacks to Diana S. Coelyn and her designees including, but not limited to, the dates and approximate amounts set forth below:

Overt Act Number	Date	Amount of Kickback
84	February 4, 2003	\$17,000.00
85	February 4, 2003	\$5,320.00
86	February 4, 2003	\$15,662.81
87	February 19, 2003	\$55,036.12
88	February 27, 2003	\$29,822.00
89	February 27, 2003	\$10,000.00
90	March 11, 2003	\$30,598.36
91	March 11, 2003	\$5,000.00
92	March 20, 2003	\$50,000.00

93. The facts of each of the separate offenses charged in Counts Two through Fifty-three are alleged to be separate overt acts undertaken in furtherance of the conspiracy and to accomplish the object of the conspiracy, and are incorporated by reference as if fully set forth herein as separate overt acts.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO

(Conspiracy to Sell Stolen Drugs)

The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.

The Origins of the Stolen Drugs

- 1. On or about December 2001, in the State of North Carolina, pharmaceutical drugs manufactured by Glaxo-Smith with a value of \$5,000.00 or more, were stolen (stolen Glaxo drugs).
- 2. On or about June 2002, in the State of Florida, pharmaceutical drugs manufactured by Roche with a value of \$5,000.00 or more, were stolen (stolen Roche drugs).

The Conspiracy and Its Objects

Beginning at a time unknown, but by no later than in or about December 2001, and continuing until at least in or about April 2003, in Kansas City, Jackson County, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Michael Allyn Carlow, Noah Salcedo-Smith, Frank Anthony Ianeillo, Gary Wayne Smith, Albert David Nassar, Salvatore A. Esposito, and Alexander Anthony Nassar did unlawfully, willfully and knowingly combine, conspire and agree with each other and with others known and unknown to the grand jury to: (a) commit offenses against the United States, that is, buy, sell, and traffic in stolen drugs, in violation of Title 18, United States Code, Section 2315, et seq., and (b) defraud the United States by impeding, obstructing, and defeating the lawful functions of the FDA to: (i) regulate the interstate sale and distribution of drugs in the United States; and, (ii) safeguard the health and safety of consumers who purchase drugs in the United States, in that the members of the conspiracy, by mutual agreement would and did buy and sell in interstate commerce drugs that they knew were stolen, all in violation of Title 18, United States Code, Section 371.

Manner and Means By Which The Conspiracy Was Carried Out

The members of the conspiracy used various manners and means to effect the object and purpose of the conspiracy, including but not limited to the following:

- 1. It was a part of the conspiracy that its members would and did purchase and sell amongst themselves drugs that they knew were stolen.
- 2. It was further a part of the conspiracy that its members would and did create false pedigrees to conceal the fact that the drugs were stolen and prevent their detection as stolen drugs.
- 3. It was further a part of the conspiracy that its members would and did sell the stolen drugs in interstate commerce, knowing that consumers ultimately would purchase the stolen drugs without knowing or suspecting that the drugs were stolen.

Overt Acts - Stolen Glaxo Drugs

- 1. In or about December 2001 the stolen Glaxo drugs were taken to a warehouse in the greater Miami, Florida area.
- 2. In or about December 2001, defendant Alexander Anthony Nassar inventoried the stolen Glaxo drugs while they were at a warehouse in the greater Miami, Florida area.
- 3. In or about December 2001, Julio Cesar Cruz faxed information about the stolen Glaxo drugs to defendant Albert David Nassar.
- 4. After receiving said fax from Julio Cesar Cruz, defendant Albert David Nassar agreed to buy the stolen Glaxo drugs.
- 5. Between on or about December 13, 2001, and January 1, 2002, defendants Salvatore A. Esposito and Albert David Nassar, d/b/a Worldwide Pharmaceuticals, purchased the stolen Glaxo drugs.
- 6. Between on or about December 13, 2001, and January 1, 2002, defendants Salvatore A. Esposito and Albert David Nassar, d/b/a Worldwide Pharmaceuticals, sold the stolen Glaxo drugs to defendant Gary Wayne Smith, d/b/a Omega Pharmaceuticals.

- 7. Between on or about December 13, 2001, and January 1, 2002, defendant Gary Wayne Smith, d/b/a Omega Pharmaceuticals, sold the stolen Glaxo drugs to defendant Frank Anthony Ianeillo, d/b/a Welcome Rx.
- 8. Between on or about December 13, 2001, and January 1, 2002, defendant Frank Anthony Ianeillo, d/b/a Welcome Rx, contracted with SoloPacific Corporation to act as his agent for the purpose of selling the stolen Glaxo drugs.
- 9. In or about January 2002, defendant Frank Anthony Ianeillo, used SoloPacific Corporation to sell the stolen Glaxo drugs to defendants Paul Louis Kriger, Noah Salcedo-Smith, Douglas C. Albers, and Albers Medical Distributors, Inc.
- 10. On or about January 2, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., purchased a portion of the stolen Glaxo drugs from SoloPacific Corporation for the sum of \$237,841.92, by sending a wire transfer in that amount to a bank account controlled by SoloPacific Corporation.
- 11. On or about January 8, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., purchased another portion of the stolen Glaxo drugs from SoloPacific Corporation for the sum of \$1,474,240.00 by sending a wire transfer in that amount to a bank account controlled by SoloPacific Corporation.
- 12. On or about January 11, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., purchased another portion of the stolen Glaxo drugs from SoloPacific Corporation for the sum of \$1,407,651.68 by sending a wire transfer in that amount to a bank account controlled by SoloPacific Corporation.
- 13. On or about January 15, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., purchased a portion of the stolen Glaxo drugs from SoloPacific

Corporation for the sum of \$200,000.00, by sending a wire transfer in that amount to a bank account controlled by SoloPacific Corporation.

- 14. On or about January 9, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to R&S Sales for \$271,397.44.
- 15. On or about January 9, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to R&S Sales for \$961,757.10.
- 16. On or about January 10, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to Rebel Distributors for \$593,730.00.
- 17. On or about January 10, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to PDI Enterprises for \$1,693,924.00.
- 18. On or about January 22, 2002, defendant Douglas C. Albers, d/b/a defendant Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to Top Source for \$13,017.60.
- 19. On or about November 26, 2002, Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to H.D. Smith for \$2,290.40.
- 20 On or about November 26, 2002, Douglas C. Albers, d/b/a Albers Medical Distributors, Inc., sold a portion of the stolen Glaxo drugs to H.D. Smith for \$499.30.

21. Between in or about January and October, 2002, defendants Douglas C. Albers and Albers Medical Distributors, Inc., paid defendant Paul Louis Kriger approximately \$106,176.96 in payment for his role in facilitating the purchase and sale of the stolen Glaxo drugs.

Overt Acts - Stolen Roche Drugs

- 1. In or about June 2002, Julio Cesar Cruz acquired control over the stolen Roche drugs in the greater Miami, Florida area.
- 2. In or about June 2002, Julio Cesar Cruz contacted defendant Paul Louis Kriger to see if Kriger wanted to purchase the stolen Roche drugs on behalf of defendant Albers Medical Distributors, Inc. During this contact, Cruz told Kriger that the drugs were stolen.
- 3. In or about June 2002, defendant Paul Louis Kriger agreed to purchase the stolen Roche drugs on behalf of Albers Medical Distributors, Inc., knowing that the drugs were stolen and knowing that Cruz could not produce a legitimate pedigree for the stolen Roche drugs.
- 4. In or about June 2002, defendant Michael Allyn Carlow, d/b/a G&K Pharma, agreed with defendant Paul Louis Kriger to use G&K Pharma as a front to purchase the stolen Roche drugs from Julio Cesar Cruz and then use G&K Pharma to resell the stolen Roche drugs to defendant Albers Medical Distributors, Inc.
- 5. On or about June 24, 2002, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger sold a portion of the stolen Roche drugs to PDI Enterprises for \$575,108.40.
- 6. On or about June 24, 2002, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger sold a portion of the stolen Roche drugs to H.D. Smith for \$271,395.00.

- 7. On or about June 24, 2002, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger sold a portion of the stolen Roche drugs to Rebel Distributors for \$868,700.14.
- 8. On or about June 26, 2002, defendants Douglas C. Albers and Albers Medical Distributors, Inc., wire transferred \$1,556,214.21, to the bank account of G&K Pharma in payment for the stolen Roche drugs.
- 9. On or about June 27, 2002, defendant Michael Allyn Carlow, d/b/a G&K Pharma, wire transferred \$1,482,102.62 to the bank account of Pharma Medical, a company and bank account controlled by Julio Cesar Cruz.
- 10. Between in or about June and July, 2002, defendants Douglas C. Albers and Albers Medical Distributors, Inc., paid defendant Paul Louis Kriger approximately \$77,584.21 in payment for his role in facilitating the purchase and sale of the stolen Roche drugs.

All in violation of Title 18, United States Code, Section 371.

COUNTS THREE THROUGH SIX

(Sale of Stolen Drugs)

- 1. The factual allegations in Count Two are incorporated herein by reference.
- 2. On or about each of the separate dates listed in Counts Three through Six below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Noah Salcedo-Smith, Frank Anthony Ianeillo, Gary Wayne Smith, Albert David Nassar, Salvatore A. Esposito, and Alexander Anthony Nassar did receive, possess, sell and dispose of, and cause the receipt, possession, sale, and disposition of, certain stolen property, knowing the same to have been stolen, that is, said defendants received, possessed, sold, and disposed of, and caused the receipt, possession, sale, and disposition of,

property consisting of a quantity of the drugs which had a value of \$5,000.00 or more, which property had crossed a State boundary after being stolen, said property having been stolen outside the State of Missouri and subsequently brought into the State of Missouri.

Count	Date	Stolen From	Drugs Sold	Buyer
3	01/09/2002	Glaxo	Imitrex, Advair, Flovent, Flonase	R & S Sales
4	01/10/2002	Glaxo	Advair, Flovent, Flonase	Rebel Distributors
5	01/10/2002	Glaxo	Advair, Flovent, Flonase	PDI Enterprises
6	01/10/2002	Glaxo	Flonase	Top Source

All in violation of Title 18, United States Code, Sections 2315 and 2.

COUNTS SEVEN THROUGH NINE

(Sale of Stolen Drugs)

- 1. The factual allegations in Count Two are incorporated herein by reference.
- 2. On or about each of the separate dates listed in Counts Seven through Nine below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Michael Allyn Carlow, and Noah Salcedo-Smith did receive, possess, sell and dispose of, and cause the receipt, possession, sale, and disposition of, certain stolen property, knowing the same to have been stolen, that is, said defendants received, possessed, sold, and disposed of, and caused the receipt, possession, sale, and disposition of, property consisting of a quantity of the drugs which had a value of \$5,000.00 or more, which property had crossed a State boundary after being stolen, said property having been stolen outside the State of Missouri and subsequently brought into the State of Missouri.

Count	Date	Stolen From	Drugs Sold	Buyer
7	06/25/2002	Roche	Soriatane	Rebel Distributors
8	06/26/2002	Roche	Accutane, Soritane	PDI Enterprises
9	07/11/2002	Roche	Accutane, Soriatane	H.D. Smith

All in violation of Title 18, United States Code, Sections 2315 and 2.

COUNTS TEN through FIFTEEN

(Sale of Counterfeit Serostim®)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. Serostim[®], an injectable human growth hormone manufactured by Serono, Inc., of Randolph, Massachusetts, was a drug within the meaning of 21 U.S.C. § 321(g)(1) and was approved for the treatment of cachexia, including AIDS-related wasting. By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Serostim[®].
- 3. On or about each of the separate dates listed below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger, sold in interstate commerce certain articles of drugs purporting to be Serostim[®], all of which were counterfeit drugs within the meaning of 21 U.S.C. § 321(g)(2), in that the containers and labeling of the drugs bore the trademark, trade name, identifying marks and imprints of Serono, Inc., without authorization from Serono, Inc., and thereby falsely purported and represented the drugs to be the product of Serono, Inc.

Date	Lot Number	Sold to	Amount Sold
07/19/2000	MNH605A	Supreme Distributors	21 boxes
07/25/2000	MNH605A	M. Sobol	30 boxes
07/31/2000	MNK612A	M. Sobol	34 boxes
08/02/2000	MNK612A	Modern Healthcare, Inc.	42 boxes
08/02/2000	MNK612A	Supreme Distributors	8 boxes
08/08/2000	MNH605A and MNK612A	M. Sobol	110 boxes total
08/14/2000	MNK612A	Supreme Distributors	43 boxes
08/17/2000	MNK612A	Modern Healthcare, Inc.	12 boxes
08/22/2000	MNK612A	R & S Sales	90 boxes
08/22/2000	MNK612A	Supreme Distributors	79 boxes
08/28/2000	MNK612A	R & S Sales	4 boxes
08/29/2000	MNH605A	Supreme Distributors	34 boxes

4. On or about each of the separate dates listed in Counts Ten through Fifteen below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger, with the intent to defraud and mislead, did sell in interstate commerce certain articles of drugs purporting to be Serostim®, all of which were counterfeit drugs within the meaning of 21 U.S.C. § 321(g)(2), in that the containers and labeling of the drugs bore the trademark, trade name, identifying marks and imprints of Serono, Inc., without authorization from Serono, Inc., and thereby falsely purported and represented the drugs to be the product of Serono, Inc.

Count	Date	Lot Number	Sold to	Amount Sold
10	09/07/2000	MNK612A	R & S Sales	15 boxes

Count	Date	Lot Number	Sold to	Amount Sold
11	09/28/2000	MNH605A	P. D. I.	45 boxes
12	10/23/2000	MNH605A	R & S Sales	1 box
13	10/31/2000	MNK612A	Modern Healthcare, Inc.	26 boxes
14	11/09/2000	MNH605A	R & S Sales	2 boxes
15	11/15/2000	MNK612A	H. D. Smith	1 box

All in violation of Title 21, United States Code, Sections 331(i)(3) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS SIXTEEN through TWENTY-ONE

(Introduction of Misbranded Serostim® into Interstate Commerce)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. Serostim[®], an injectable human growth hormone manufactured by Serono, Inc., of Randolph, Massachusetts, was a drug within the meaning of 21 U.S.C. § 321(g)(1) and was approved for the treatment of cachexia, including AIDS-related wasting. By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Serostim[®].
- 3. On or about each of the separate dates listed below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger, introduced and delivered for introduction into interstate commerce certain articles of drugs purporting to be Serostim[®], all of which were misbranded drugs within the meaning of 21 U.S.C. § 352(a), in that drugs, labeled as Serostim[®], bore a lot number, MNH605A, which

was false, in that no such lot number was assigned by Serono, Inc., to any authentic Serostim[®], and the drugs labeled with lot number MNK612A bore an expiration date different from and unrelated to that of the authentic Serostim[®], Lot MNK612A, manufactured by Serono, Inc.

Date	Lot Number	Sold to	Amount Sold
07/19/2000	MNH605A	Supreme Distributors	21 boxes
07/25/2000	MNH605A	M. Sobol	30 boxes
07/31/2000	MNK612A	M. Sobol	34 boxes
08/02/2000	MNK612A	Modern Healthcare, Inc.	42 boxes
08/02/2000	MNK612A	Supreme Distributors	8 boxes
08/08/2000	MNH605A and MNK612A	M. Sobol	110 boxes total
08/14/2000	MNK612A	Supreme Distributors	43 boxes
08/17/2000	MNK612A	Modern Healthcare, Inc.	12 boxes
08/22/2000	MNK612A	R & S Sales	90 boxes
08/22/2000	MNK612A	Supreme Distributors	79 boxes
08/28/2000	MNK612A	R & S Sales	4 boxes
08/29/2000	MNH605A	Supreme Distributors	34 boxes

4. On or about each of the separate dates listed in Counts Sixteen through Twenty-one below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Louis Kriger, with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce certain articles of drugs purporting to be Serostim®, all of which were misbranded drugs within the meaning of 21 U.S.C. § 352(a), in that the drugs' labeling was false and misleading in any particular, to-wit, the drugs labeled as Serostim®, bore a lot number, MNH605A, which was false, in that no such lot number was assigned by Serono, Inc., to any authentic Serostim®, and the drugs labeled with lot number MNK612A bore

an expiration date different from and unrelated to that of the authentic Serostim[®], Lot MNK612A, manufactured by Serono, Inc.

Count	Date	Lot Number	Sold to	Amount Sold
16	09/07/2000	MNK612A	R & S Sales	15 boxes
17	09/28/2000	MNH605A	P. D. I.	45 boxes
18	10/23/2000	MNH605A	R & S Sales	1 box
19	10/31/2000	MNK612A	Modern Healthcare, Inc.	26 boxes
20	11/09/2000	MNH605A	R & S Sales	2 boxes
21	11/15/2000	MNK612A	H. D. Smith	1 box

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS TWENTY-TWO through TWENTY-SEVEN

(Sale of Counterfeit Neupogen®)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. Neupogen®, an injectable human granulocyte colony stimulating factor ("G-CSF") manufactured by Amgen, Inc., of Thousand Oaks, California, was a drug within the meaning of 21 U.S.C. § 321(g)(1) and was approved for use, among other things, in stimulating the production of white blood cells in order to decrease the incidence of infections in persons with lowered immune systems, such as cancer patients receiving chemotherapy. By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Neupogen®.

3. On or about each of the separate dates listed in Counts Twenty-two through Twenty-seven below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Kriger, with the intent to defraud and mislead, did sell in interstate commerce certain articles of drugs purporting to be Neupogen[®], all of which were counterfeit drugs within the meaning of 21 U.S.C. § 321(g)(2), in that the containers and labeling of the drugs bore the trademark, trade name, identifying marks and imprints of Amgen, Inc., without authorization from Amgen, Inc., and were thereby falsely purported and represented to be the product of Amgen, Inc.

Count	Date	Lot Number	Sold to	Amount Sold
22	04/05/2001	P000890	Top Source	1 box
23	04/11/2001	P000890	Top Source	14 boxes
24	04/19/2001	P000890	Top Source	21 boxes
25	04/24/2001	P000890	H. D. Smith	18 boxes
26	05/21/2001	P000948	H. D. Smith	2 boxes
27	09/25/2001	P000954	Actsys Medical	2 boxes

All in violation of Title 21, United States Code, Sections 331(i)(3) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS TWENTY-EIGHT through THIRTY-THREE

(Introduction of Misbranded Neupogen® into Interstate Commerce)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. On or about each of the separate dates listed in Counts Twenty-eight through Thirty-three below, within the Western District of Missouri and elsewhere, defendants Douglas C.

Albers, Albers Medical Distributors, Inc., and Paul Kriger, with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce certain articles of drugs purporting to be Neupogen®, all of which were misbranded drugs within the meaning of 21 U.S.C. § 352(a), in that drugs' labeling was false and misleading in any particular, to-wit, the drugs labeled as Neupogen®, bearing lot numbers P000948 and P000954, were false, in that no such lot numbers were assigned by Amgen, Inc. to any authentic Neupogen®, and drugs labeled with lot number P000890 bore an expiration date different from and unrelated to that of the authentic Neupogen®, Lot P000890, manufactured by Amgen, Inc.

Count	Date	Lot Number	Sold to	Amount Sold
28	04/05/2001	P000890	Top Source	1 box
29	04/11/2001	P000890	Top Source	14 boxes
30	04/19/2001	P000890	Top Source	21 boxes
31	04/24/2001	P000890	H. D. Smith	18 boxes
32	05/21/2001	P000948	H. D. Smith	2 boxes
33	09/25/2001	P000954	Actsys Medical	2 boxes

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS THIRTY-FOUR AND THIRTY-FIVE

(Holding for Sale of Counterfeit Procrit®)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. Procrit[®], manufactured by Amgen, Inc., of Thousand Oaks, California, and distributed by Ortho Biotech Products of Raritan, New Jersey, was an injectable drug within the meaning of 21

U.S.C. § 321(g)(1) and was approved for, among other things, the treatment of anemia in patients with chronic renal failure and AIDS. By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Procrit®.

3. On or about each of the separate dates listed in Counts Thirty-four and Thirty-five below, within the Western District of Missouri, defendants Douglas C. Albers, Albers Medical Distributors, Inc., and Paul Kriger, with the intent to defraud and mislead, did hold for sale in interstate commerce certain articles of drugs purporting to be Procrit®, all of which were counterfeit drugs within the meaning of 21 U.S.C. § 321(g)(2), in that the containers and labeling of the drugs bore the trademark, trade name, identifying marks and imprints of Amgen, Inc., and Ortho Biotech Products, without authorization from Amgen, Inc., and Ortho Biotech Products, and thereby falsely purported and represented to be the product of Amgen, Inc., and falsely purported and represented to be distributed by Ortho Biotech Products.

Count	Date	Lot Number
34	03/12/2003	P0004677
35	03/12/2003	P0007645

All in violation of Title 21, United States Code, Sections 331(i)(3) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS THIRTY-SIX through THIRTY-NINE

(Sale of Counterfeit Lipitor®)

1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.

- 2. Lipitor®, a cholesterol reduction medication manufactured by Pfizer, was a drug within the meaning of 21 U.S.C. § 321(g)(1). By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Lipitor®.
- 3. Each of the sales identified in Counts Thirty-six through Thirty-nine contained counterfeit Lipitor®tablets that had been commingled with Pfizer-manufactured Lipitor®tablets not intended or approved for sale in the United States that had been illegally imported into the United States.
- 4. The counterfeit Lipitor® tablets and the Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States were repackaged at the facilities of defendant Med-Pro, Inc.
- 5. On or about each of the separate dates listed in Counts Thirty-six through Thirty-nine below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Michael Allyn Carlow, Richard K. Rounsborg, and Med-Pro, Inc., with the intent to defraud and mislead, sold, caused, and aided and abetted the sale in interstate commerce of certain articles of drugs, namely tablets of purported Lipitor® which were counterfeit drugs within the meaning of Title 21, United States Code, Section 321(g)(2), in that, without proper authorization, said tablets bore the trademark, trade name and other identifying marks of Pfizer-manufactured Lipitor® approved for sale in the United States and were thereby falsely represented to be Pfizer-manufactured Lipitor® approved for sale in the United States.

Count	Date	Repackaged By	Sold to	Amount of Sale
36	11/15/2002	Med-Pro	Americhoice and H.D. Smith	\$1,706,348.00

Count	Date	Repackaged By	Sold to	Amount of Sale
37	11/27/2002	Med-Pro	Americhoice, H.D. Smith, and Seacoast	\$1,699,154.44
38	12/10/2002	Med-Pro	Americhoice and H.D. Smith	\$1,664,479.00
39	12/12/2002	Med-Pro	H.D. Smith	\$1,683,551.00

All in violation of Title 21, United States Code, Sections 331(i)(3) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNTS FORTY through FORTY-FOUR

(Sale of Counterfeit Lipitor®)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. Lipitor®, a cholesterol reduction medication manufactured by Pfizer, was a drug within the meaning of 21 U.S.C. § 321(g)(1). By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Lipitor®.
- 3. Each of the sales identified in Counts Forty through Forty-four contained counterfeit Lipitor® tablets that had been commingled with Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States.
- 4. The counterfeit Lipitor® tablets and the Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States were repackaged at the facilities of NuCare Pharmaceuticals and defendant Med-Pro, Inc.

5. On or about each of the separate dates listed in Counts Forty through Forty-four below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Michael Allyn Carlow, Christopher Wayne Lamoreaux, Richard K. Rounsborg, and Med-Pro, Inc., with the intent to defraud and mislead, sold, caused, and aided and abetted the sale in interstate commerce of certain articles of drugs, namely tablets of purported Lipitor® which were counterfeit drugs within the meaning of Title 21, United States Code, Section 321(g)(2), in that, without proper authorization, said tablets bore the trademark, trade name and other identifying marks of Pfizer-manufactured Lipitor® approved for sale in the United States and were thereby falsely represented to be Pfizer-manufactured Lipitor® approved for sale in the United States.

Count	Date	Repackaged By	Sold to	Amount of Sale
40	01/14/2003	Med-Pro and NuCare	H.D. Smith	\$2,646,787.00
41	01/20/2003	Med-Pro and NuCare	Americhoice and H.D. Smith	\$2,532,611.00
42	02/26/2003	Med-Pro and NuCare	Americhoice, H.D. Smith, Metro Drugs, DBS Trading, and Top Source	\$1,990,232.16
43	03/03/2003	Med-Pro and NuCare	H.D. Smith	\$2,304,554.34
44	03/14/2003	Med-Pro and NuCare	Americhoice and H.D. Smith	\$2,767,681.42

All in violation of Title 21, United States Code, Sections 331(i)(3) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNTS FORTY-FIVE through FORTY-EIGHT

(Introduction of an Unapproved New Drug Into Interstate Commerce)

- 1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.
- 2. Lipitor®, a cholesterol reduction medication manufactured by Pfizer, was a drug within the meaning of 21 U.S.C. § 321(g)(1) and a new drug within the meaning of 21 U.S.C. § 321(p). A new drug must be mixed and packaged in conformity with the FDA-approved New Drug Application (NDA) used to approve use of a new drug in the United States. By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Lipitor®.
- 3. Each of the sales identified in Counts Forty-five through Forty-eight contained counterfeit Lipitor®tablets that had been commingled with Pfizer-manufactured Lipitor®tablets not intended or approved for sale in the United States that had been illegally imported into the United States.
- 4. The counterfeit Lipitor® tablets and the Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States were repackaged at the facilities of defendant Med-Pro, Inc.
- 5. The Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States were unapproved new drugs within the meaning of 21 U.S.C. § 355 in that said tablets were originally packaged at a facility outside the United States not listed on the FDA-approved NDA for Lipitor®.
- 6. On or about each of the separate dates listed in Forty-five through Forty-eight below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers

Med-Pro, Inc., with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce an unapproved new drug, that is, certain articles of drugs purporting to be Lipitor® approved for sale in the United States that had been repackaged with a label that concealed and disguised the fact that the drugs had been originally packaged at a facility outside the United States not listed on the FDA-approved New Drug Application for Lipitor®, and thereby falsely represented that the drugs had been lawfully packaged for sale in the United States, and falsely represented that the drugs were approved for sale in the United States.

Count	Date	Repackaged By	Sold to	Amount of Sale
45	11/15/2002	Med-Pro	Americhoice and H.D. Smith	\$1,706,348.00
46	11/27/2002	Med-Pro	Americhoice, H.D. Smith, and Seacoast	\$1,699,154.44
47	12/10/2002	Med-Pro	Americhoice and H.D. Smith	\$1,664,479.00
48	12/12/2002	Med-Pro	H.D. Smith	\$1,683,551.00

All in violation of Title 21, United States Code, Sections 331(d) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNTS FORTY-NINE through FIFTY-THREE

(Introduction of an Unapproved New Drug Into Interstate Commerce)

1. The factual allegations in Paragraphs One through Thirty-nine of the Introduction and Background section of this indictment are incorporated herein by reference as if fully set forth herein.

- 2. Lipitor®, a cholesterol reduction medication manufactured by Pfizer, was a drug within the meaning of 21 U.S.C. § 321(g)(1) and a new drug within the meaning of 21 U.S.C. § 321(p). A new drug must be mixed and packaged in conformity with the FDA-approved New Drug Application (NDA) used to approve use of a new drug in the United States. By virtue of his status as a trained and licensed pharmacist, defendant Douglas C. Albers knew and should have known the approved and intended uses of Lipitor®.
- 3. Each of the sales identified in Counts Forty-nine through Fifty-three contained counterfeit Lipitor®tablets that had been commingled with Pfizer-manufactured Lipitor®tablets not intended or approved for sale in the United States that had been illegally imported into the United States.
- 4. The counterfeit Lipitor® tablets and the Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States were repackaged at the facilities of NuCare Pharmaceuticals and defendant Med-Pro, Inc.
- 5. The Pfizer-manufactured Lipitor® tablets not intended or approved for sale in the United States that had been illegally imported into the United States were unapproved new drugs within the meaning of 21 U.S.C. § 355 in that said tablets were originally packaged at a facility outside the United States not listed on the FDA-approved NDA for Lipitor®.
- 6. On or about each of the separate dates listed in Forty-nine through Fifty-three below, within the Western District of Missouri and elsewhere, defendants Douglas C. Albers, Albers Medical Distributors, Inc., Paul Louis Kriger, Michael Allyn Carlow, Richard K. Rounsborg, Med-Pro, Inc., and Christopher Wayne Lamoreaux, with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce an unapproved new drug, that is,

certain articles of drugs purporting to be Lipitor® approved for sale in the United States that had been repackaged with a label that concealed and disguised the fact that the drugs had been originally packaged at a facility outside the United States not listed on the FDA-approved New Drug Application for Lipitor®, and thereby falsely represented that the drugs had been lawfully packaged for sale in the United States, and falsely represented that the drugs were approved for sale in the United States.

Count	Date	Repackaged By	Sold to	Amount of Sale
49	01/14/2003	Med-Pro and NuCare	H.D. Smith	\$2,646,787.00
50	01/20/2003	Med-Pro and NuCare	Americhoice and H.D. Smith	\$2,532,611.00
51	02/26/2003	Med-Pro and NuCare	Americhoice, H.D. Smith, Metro Drugs, DBS Trading, and Top Source	\$1,990,232.16
52	03/03/2003	Med-Pro and NuCare	H.D. Smith	\$2,304,554.34
53	03/14/2003	Med-Pro and NuCare	Americhoice and H.D. Smith	\$2,767,681.42

All in violation of Title 21, United States Code, Sections 331(d) and 333(a)(2) and Title 18, United States Code, Section 2.

Dated this	day of		, 2005.	
		A TRUE BILL:		

FOREPERSON OF THE GRAND JURY

Phillip Eugene Porter Senior Litigation Counsel